

K132636

Endoscopy
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92
upon which the substantial equivalence is based.

DYONICS PLAN Hip Impingement Planning System

Date Prepared: August 21, 2013

OCT 17 2013

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road, Andover MA. 01810

B. Company Contact

Kathleen Solomon
Sr. Regulatory Affairs Specialist
T 978-749-1605
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C. Device Name

Trade Name: DYONICS PLAN Hip Impingement Planning System
Common Name: Hip Impingement Planning System
Classification Name: Picture archiving and communications system per CFR
882.2050

D. Predicate Devices

The Smith & Nephew DYONICS PLAN is substantially equivalent in Intended Use
and Fundamental Scientific Technology to the following legally marketed device in
commercial distribution: Mimics cleared in K073468.

E. Description of Device

The Smith & Nephew DYONICS PLAN Hip Impingement Planning System (here in after referred to as DYONICS PLAN software) is a software product that allows orthopedic surgeons and other healthcare professionals to visualize and perform analysis of digital images for assessment of hip preservation treatment options pre-operatively or post-operatively. The software enables the user to import computed tomography (CT) images, display various 2D views of the images, execute image segmentation and 3D rendering of the femur and pelvis, generate anatomic measurements, identify the areas and degree of conflict and simulate the resection of bony lesions, perform a dynamic range of motion analysis of the hip joint, and export the results in an output report. The software automatically generates a default estimate for each step of the analysis based on published literature, and the surgeon should always verify and make adjustments of the parameters based on their clinical judgment. The purpose of the software is to support other clinical findings and patient examination when assessing hip preservation treatment options.

The software is designed to be installed and run locally on a PC-compatible personal computer with a Windows operating system and a graphics card that meets the specified minimum requirements. The software facilitates the importation of CT images in DICOM format and allows the export of the output report in PDF or HTML format which can be referenced pre-operatively, intra-operatively or post-operatively. The user is provided with installation instructions which include the following: a link to a secure website, steps to download the installation file along with a license activation code and password.

F. Intended Use

The DYONICS PLAN is intended as pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review, respectively.

G. Comparison of Technological Characteristics

The proposed DYONICS PLAN has the following similarities as the predicate device Mimics cleared in K073468. In that:

- The proposed and predicate devices both have the same intended use: surgical planning tool
- The proposed and predicate devices both utilize the same principle of operation: stand-alone software for computer assisted surgical planning
- The proposed and predicate devices both import CT scans in DICOM format
- The proposed and predicate devices both provide image processing tools, including image segmentation and 3D rendering tools
- The proposed and predicate devices both provide measurement tools

- The proposed and predicate devices both have tools for surgical simulation and planning

The major differences between the proposed DYONICS PLAN and the predicate device Mimics are:

- The DYONICS PLAN is only indicated for surgical planning for hip preservation treatment options whereas Mimics is for general surgical planning
- The DYONICS PLAN provides output report which can be referenced pre-operatively, intra-operatively or post-operatively.
- Mimics uses additional image formats such as JPEG, TIFF, BMP, or Raw image data
- In addition to CT scans, Mimics can also import MRI scans.

The differences between the proposed and predicate device does not introduce new types of safety or effectiveness questions. The DYONICS PLAN is only a pre-planning surgical tool that provides surgeons an additional method for planning hip preservation surgeries.

H. Summary Performance Data

Software verification and validation testing demonstrates that the DYONICS PLAN does not raise any new questions of safety and efficacy as compared to the predicate device Mimics cleared in K073468.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

KATHLEEN SOLOMON
SMITH & NEPHEW, INC.
SR. RA SPECIALIST
150 MINUTEMAN RD.
ANDOVER MA 01810

Re: K132636

Trade/Device Name: DYONICS PLAN Hip Impingement Planning System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 21, 2013
Received: August 22, 2013

Dear Ms. Solomon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

**Premarket Notification
Indications for Use Statement**

510(k) Number (if known): K132636

Device Name: DYONICS PLAN Hip Impingement Planning System

Indications for Use:

The DYONICS PLAN Hip Impingement Planning System software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative or post-operative software for simulating/evaluating hip preservation surgical treatment options and historical case review, respectively.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

